

## REMARKS

Reconsideration and allowance of the above-referenced application are respectfully requested. Applicant petitions for a three-month extension of time to reply to the Office Action mailed March 17, 2011. Reconsideration of the application is respectfully requested.

**Summary of Rejections.** The Office has rejected claims 19 and 21 under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement; rejected claims 19, 21, and 31 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,626,559 to Solomon (hereinafter "Solomon"); rejected claim 20 under 35 U.S.C. §103(a) as allegedly being unpatentably obvious over Solomon in view of U.S. Patent No. 5,743,868 to Brown et al. (hereinafter "Brown"); and rejected claims 32 and 33 under 35 U.S.C. §103(a) as allegedly being unpatentably obvious over Solomon in view of U.S. Patent No. 6,468,283 to Richter et al. (hereinafter "Richter").

**Summary of Amendments.** With this amendment, claims 19 and 21 have been amended. Claims 32 and 33 have been cancelled without prejudice or disclaimer. The subject matter of now cancelled claims 32 and 33 has been added to corresponding independent claims. The amendments are fully supported by the original specification, at least at FIG. 3 and associated text.

No new matter has been added with this amendment.

**Rejection under 35 U.S.C. §112**

Claims 19 and 21 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

Specifically, the Office alleges on page 3 of the Office Action that the specification does not specifically state that the distal region of the implant is cone-shaped such that the diameter of the distal region gradually reduces moving in the distal direction. In response, Applicant submits a formal version of the figures. Applicant notes that now submitted FIGURE 3 clearly shows an implant wherein the distal region of the implant is cone-shaped such that the diameter of the distal region gradually reduces moving in the distal direction. In view of the foregoing, it is respectfully requested that the rejection under 35 U.S.C. 112, first paragraph of claims 19 and 21 should be withdrawn.

**Rejection under 35 U.S.C. §102(b)**

Claims 19, 21, and 31 stand rejected under 35 U.S.C. §102(b) as allegedly being allegedly being anticipated by Solomon. This rejection is respectfully traversed.

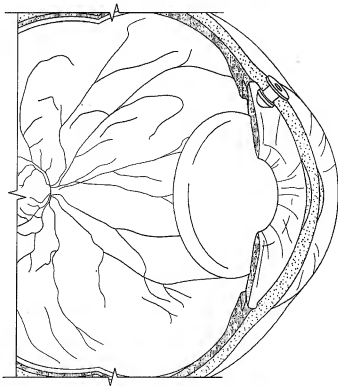
To present a valid anticipation rejection under 35 U.S.C. §102, the Office must identify a single prior art reference in which “each and every element as set forth in the claim is found, either expressly or inherently described.” As discussed in greater detail below, Solomon fails to disclose or even to fairly suggest at least the below-noted limitations of the currently presented claims.

Amended claim 19 recites the following features:

An ocular pressure spike shunt for insertion into an ocular paracentesis incision port following ocular surgery, comprising a flexible fluid transfer tube formed of biocompatible material so as to allow paracentesis incision closure around said tube, having a distal region on an inner surface of a cornea and a proximal end on an outer surface of the cornea, a tubular portion having a lumen, the tubular portion disposed between said distal region and said proximal end to allow fluid communication through said tube, wherein said distal region and proximal end both have an enlarged diameter relative to a diameter of a central section of said shunt, and wherein said distal region is cone-shaped such that the diameter of the distal region gradually reduces moving in a distal direction and *a distal-most end of the distal region is curved*, said lumen containing a valve for controlling pressure in the eye following ocular surgery, which valve opens permitting fluid flow through said tube when a predetermined pressure is exceeded, said shunt being configured such that on insertion into a paracentesis port said proximal end is flush with the outer surface of the cornea and a portion of the enlarged diameter of the distal region is positioned flat against the inner surface of the cornea, and said distal region opens into the anterior chamber of the eye, wherein the tube is removable from the eye, *the proximal end having a flat outer surface that lies flush with the surface of the cornea when the pressure spike is implanted, the flat outer surface being perpendicular to the tubular portion.*

Emphasis added.

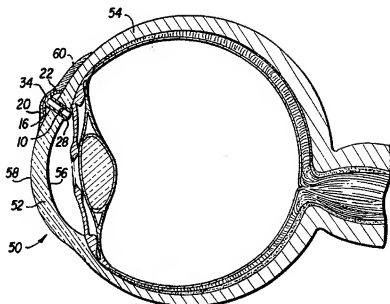
In some implementations consistent with claim 19, an ocular pressure spike shunt in accordance with specification at least at FIGURE 3 (shown below) is described.



Original specification at FIGURE 3

As shown above, the ocular pressure spike shunt has a distal region on an inner surface of cornea and a proximal end on an outer surface of the cornea. The distal region is cone-shaped such that the diameter of the distal region gradually reduces moving in a distal direction and the distal-most end of the distal region is curved. The proximal end has a flat outer surface that lies flush with the surface of the cornea when the pressure spike is implanted. The flat outer surface is perpendicular to the tubular portion.

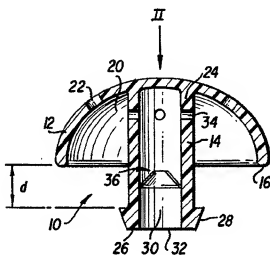
In contrast to claim 19, Solomon describes an ophthalmic device for draining excess intraocular fluid. This ophthalmic device is placed in the eye as shown by Solomon at FIG. 5 shown below.



**FIG. 5**

Solomon at FIG. 5

The above-mentioned ophthalmic device is further shown in Solomon at FIGS. 1 (shown below) and 3.



**FIG. 1**

Solomon at FIG. 1

As shown above by Solomon at FIGS. 1 and 5, the distal-most end (flat surface at bottom of Solomon at FIG. 1) of the distal region (i.e. region towards inside of the eye) is flat rather than being *curved*, as required by amended claim 19. Therefore, Solomon fails to disclose or suggest the following feature of claim 19: "wherein said distal region is cone-shaped such that the diameter of the distal region gradually reduces moving in a distal direction and the distal-most end of the distal region is *curved*."

Further, claim 19 has been amended to include the features of now cancelled claim 33. Accordingly, claim 19 recites, inter alia, the following feature: "the proximal end having a flat outer surface that lies flush with the surface of the cornea when the pressure spike is implanted." With respect to now cancelled claim 33, the Office acknowledges on page 7 of the Office Action that Solomon fails to disclose or suggest the aforementioned feature. To cure this deficiency of Solomon, the Office relies on Richter.

In contrast to the above-mentioned feature of claim 19, Richter describes an implant, as shown by Richter at FIG. 2 shown below.

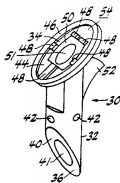


FIG. 2

Richter at FIG. 2

This implant comprises a rounded disc 34 attached to tube 32. This disc 34 lies over the sclera, as acknowledged by the Office on page 7 of the Office Action.

The Office asserts on page 7 of the Office Action that Richter's rounded disc lying over sclera constitutes the following feature of claim 19: "the proximal end having a flat outer surface that lies flush with the surface of the cornea when the pressure spike is implanted." This assertion is respectfully traversed as follows.

Claim 19 requires the flat outer surface to lie flush with surface of the *cornea*, rather than flush with surface of sclera. Emphasis added. On the contrary, Richter's rounded disc lying over sclera, as acknowledged by the Office on page 7 of the Office Action, does not constitute the above-referred feature of claim 19. For at least this reason, Richter fails to disclose or suggest this above-referred feature of claim 19.

To further differentiate from Richter, claim 19 has been amended to recite the following limitation: "the flat outer surface being perpendicular to the tubular portion." Contrary to this limitation, as noted above by Richter at FIG. 2, the rounded disc 34 is not perpendicular to tube 32. Rather, the rounded disc 34 is at an angle significantly different than 90 degrees to tube 32. For at least this reason, Richter fails to disclose or suggest the above-noted limitation of claim 19.

In view of the points noted above, claim 19 is allowable over Solomon and Richter, whether taken individually or in combination. Therefore, the rejection under 35 U.S.C. §102(b) of claim 19 should be withdrawn.

Independent claim 21, although of different scope, includes features similar to those recited above with respect to claim 19. Accordingly, claim 21, and claim 31, at least by reason of dependency, are allowable over Solomon and Richter, whether taken individually or in combination. Therefore, the rejection under 35 U.S.C. §102(b) of claims 21 and 31 should be withdrawn.

**Rejection under 35 U.S.C. §103(a)**

Claim 20 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentably obvious over Solomon in view of Brown.

For a proper rejection under 35 U.S.C. §103(a), the Office “bears the initial burden of factually supporting any *prima facie* conclusion of obviousness” and must therefore present “a clear articulation of the reason(s) why the claimed invention would have been obvious.” This rationale must include a showing that all of the claimed elements were known in the prior art and that one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, to produce a combination yielding nothing more than predictable results to one of ordinary skill in the art. MPEP §2141.02 further notes that “a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. The rejection fails to satisfy this burden with regards to the currently pending claims.

Claim 20 depends from claim 19, and includes all the features recited therein. Further, it is submitted that Brown fails to cure the above-noted deficiencies of Solomon and Richter.



Therefore, claim 20 is allowable over Solomon, Richter, and Brown whether taken individually or in combination, and the rejection under 35 U.S.C. §103(a) of claim 20 should be withdrawn for at least this reason.

### **CONCLUSION**

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper.

In view of the above amendments and remarks, reconsideration and allowance of the application are respectfully requested.

Authorization for a credit card payment of the total filing fee is submitted herewith. No additional fees are believed to be due, however, the Commissioner is authorized to charge any

Applicant : Minas Theodore Coroneo  
Serial No. : 10/579,330  
Filed : August 8, 2006  
Page : 14 of 14

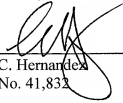
Attorney's Docket No.: 37528-503N01US

additional fees or credit overpayments to Deposit Account No. 50-0311.

Respectfully submitted,

Date: \_\_\_\_\_

September 14, 2011

  
\_\_\_\_\_  
Fred C. Hernandez  
Reg. No. 41,832

**PTO Customer No. 64046**

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
3580 Carmel Mountain Road, Suite 300  
San Diego, CA 92130  
Telephone: (858) 314-1518  
Fax: (858) 314-1501  
Email: fhernandez@mintz.com